State of California—Health and Human Services Agency
California Department of Public Health

MARK B HORTON, MD, MSPH
Director

ARNOLD SCHWARZENEGGER
Governor

Information Notice

October 25, 2010

To: Radioactive Materials Licensees

Subject: Adoption of Title 10, Code of Federal Regulations, Part 35 (10 CFR 35)

To maintain compatibility with the US Nuclear Regulatory Commission (NRC) and other Agreement States that have adopted 10 CFR 35, the California Department of Public Health (CDPH) has adopted relevant sections of 10 CFR 35. The adoption of these regulations has been approved by the Office of Administrative Law, with an effective date of January 1, 2011. A copy of 10 CFR 35, (January 1, 2008), is available at: http://www.access.gpo.gov/nara/cfr/waisidx_08/10cfr35_08.html.

This information notice is the second in a series of information notices, designed to inform licensees of changes which will occur as a result of the adoption of 10 CFR 35, and also of how the Radiologic Health Branch (RHB) expects licensees to respond to the changes. Information notices such as this will be posted on RHB's Radioactive Materials Licensing webpage under "Hot Topics" at: http://www.cdph.ca.gov/certlic/radquip/Pages/RadioactiveMaterials.aspx.

The following information is provided to specifically call out regulatory changes, and to provide clarifications regarding some of the new regulations that licensees may find applicable to their operations and radiation safety programs.

- While the State of California plans to adopt 10 CFR 35, the statements, representations, and procedures specified in a licensee's application, correspondence and actual license will continue to govern if they are more restrictive than the regulations in 10 CFR 35.

- All license amendment requests submitted prior to January 1, 2011, will follow current CDPH policies and standards. After January 1, 2011, California accepted 10 CFR 35 policies and standards will apply.

- In accordance with 10 CFR 35.40, the administration of Iodine-131 (I-131) in doses greater than 30 microcuries requires a written directive. This change may affect physicians who are currently authorized for the use of I-131 for diagnostic imaging under Groups 2 and 3, but who may now not meet the training and experience requirements of 10 CFR 35.300. Group 2 and 3 physicians who wish to be grandfathered for purposes of an authorization to administer I-131, requiring a written directive, for diagnostic imaging, must submit an amendment request before January 1, 2011. Attachment 1 should be used to submit your amendment request for grandfathering. After January 1, 2011, Attachment 1 cannot be used to submit an amendment request to authorize a physician to administer I-131, requiring a written directive for diagnostic imaging.

- Presently, the State of California does not require a radioactive materials licensee with authorization for use of either a high dose rate (HDR) remote afterloader or a Strontium 90 Eye Applicator to list their Authorized Medical Physicist (AMP) on the license. In the future, an AMP who operates the devices must be named on the license as a HDR or Applicator user. If your facility is currently authorized for an HDR or Applicator and you do not currently have your AMP listed on your license, you must submit an amendment request to grandfather the AMP before January 1, 2011. Attachment 2 should be used to submit your amendment request for grandfathering. After January 1, 2011, Attachment 2 cannot be used to name an AMP to the license.

- In accordance with 10 CFR 35.615(f)(2), the use of an HDR remote afterloader will require the Authorized User (AU) and AMP to be physically present (within hearing distance of normal voice) during the initiation of all patient treatments involving the unit. In addition, the AMP and either an AU or a physician, under the supervision of an AU who has been trained in the unit's operation and emergency response for the unit, must be physically present during the continuation of all patient treatments involving the HDR remote afterloader unit.

- After the adoption of 10 CFR 35, California medical radioactive materials licenses will be modified to reflect the NRC classifications regarding use authorizations. For example, rather than authorizations for Groups 1, 2, 3, etc., licenses will be rewritten for authorizations for 10 CFR 35.100, 10 CFR 35.200, etc.

Questions and comments may be submitted to Ira.Schneider@cdph.ca.gov.

Sincerely,

Original Signed By Ira Schneider

Ira Schneider
Senior Health Physicist
Radiologic Health Branch
(916) 440-7976

Attachment 1

Request for Administration of Iodine-131 Requiring a Written Directive for Diagnostic Imaging for Groups 2 and 3 Physician Authorized Users (Iodine-131 Administration Greater Than 30 microcuries)

Please add Dr. _____

to Radioactive Materials License Number _____

as a physician* who is authorized for the administration of Iodine-131, requiring a written directive. I certify that the above named physician has been performing uptake studies of Iodine-131, requiring a written directive, under this radioactive materials license:

_____	_____	_____
RSO Print Name	RSO Signature	Date
_____	_____	_____
Physician Print Name	Physician Signature	Date

*Complete for each Physician and return the form only (no other paperwork is necessary) to the Radiologic Health Branch at:

CDPH
Radiologic Health Branch
P.O. Box 997414, MS 7610
Sacramento, CA 95899-7414

Attachment 2

Request for Authorized Medical Physicist Listing on Radioactive Materials License

Please add _____

to Radioactive Materials License Number _____

as an Authorized Medical Physicist (AMP)*. I certify that the above named individual has sufficient training and experience, as well as appropriate educational credentials and is adequately qualified to perform the functions of an AMP for following devices(s) noted below:

- ☐ Strontium-90 Eye Applicator
- ☐ High Dose Rate Afterloader Units
- ☐ Gamma Strereotactic Radiosurgery Units (Gammaknife)
- ☐ Teletherapy Devices (Radioactive Material Only)

_____	_____	_____
RSO Print Name	RSO Signature	Date
_____	_____	_____
AMP Print Name	AMP Signature	Date

*Complete for each AMP and return the form only (no other paperwork is necessary) to the Radiologic Health Branch at:

CDPH
Radiologic Health Branch
P.O. Box 997414, MS 7610
Sacramento, CA 95899-7414